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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,837	06/24/2003	Hua Shi	19603/3921 (CRF D-2944A)	8111
7590	03/16/2006		EXAMINER	
Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051			THOMAS, DAVID C	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 03/16/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/602,837	Applicant(s) SHI ET AL.	
	Examiner David C. Thomas	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-22, drawn to methods of identifying RNA ligands, classified in class 435, subclass 6.
 - II. Claims 23-32, drawn to oligoDNA molecules that hybridize to RNA ligands and a kit for selecting RNA ligands comprising a matrix for partitioning RNA ligands, oligoDNA molecules that hybridize to RNA ligands, and an RNaseH enzyme, classified in class 536, subclass 23.1 and class 435, subclasses 183 and 295.3.
 - III. Claims 33-38, drawn to a nucleic acid aptamer that binds to a heat shock factor protein, classified in class 435, subclass 23.1.
 - IV. Claims 39-46, drawn to methods of modifying activity of a heat shock factor protein, classified in class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions in Groups II and Group I are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group II, drawn to oligoDNA molecules that hybridize to RNA ligands and a kit for selecting RNA ligands comprising a matrix for partitioning RNA ligands, oligoDNA molecules that

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hybridize to RNA ligands, and an RNaseH enzyme, can be used in other processes in addition to the methods of Group I, such as detection of target RNA or DNA for various DNA diagnostic applications and probing nucleic acid sequences with or without isolation on a matrix.

4. Inventions in Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the methods of identifying RNA ligands in Group I can be used to make other nucleic acid aptamers in addition to those for a heat shock factor protein, while the nucleic acid aptamer of Group III can be made by other methods.

5. Inventions in Group I and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation and different functions. The methods of identifying RNA ligands of Group I can be used for identifying and isolating RNA ligands that bind various targets, while the methods of modifying activity of a heat shock factor protein of Group IV are used for binding a specific aptamer to a specific target, in this case a heat shock protein.

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6. Inventions in Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the oligoDNA molecules that hybridize to RNA ligands and a kit for selecting RNA ligands comprising a matrix for partitioning RNA ligands, oligoDNA molecules that hybridize to RNA ligands, and an RNaseH enzyme of Group II are used for identifying and isolating RNA aptamers, while Group IV is drawn to using a specific RNA aptamer to modify the activity of a target, a heat shock factor protein, and thus the inventions have different functions and modes of operation.

7. Inventions in Group II and Group III are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a materially different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the aptamers of Group III can be made by another apparatus or kit, and the apparatus can be used for making other products such as RNA or DNA probes for various DNA diagnostic applications.

8. Inventions in Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

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different process of using that product (MPEP § 806.05(h)). In the instant case, the method for modifying the activity of a heat shock protein of Group IV can be practiced with other reagents that bind to heat shock proteins such as antibodies or with other techniques including heat shock.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, searching the inventions of Groups I-IV together would impose serious search burden. The inventions of Groups I-IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods of identifying and using RNA ligands as well as kits and reagents for identifying such ligands are not coextensive.

Sequence Restriction

10. This application contains claims directed to 16 patentably distinct inventions, specifically, the individual SEQ ID Nos. 5-14 (oligoDNA molecules) and 31-36 (nucleic acid aptamers). Furthermore, the sequence searching in multiple expansive databases has put undue burden on the examiner and office resources. After election of one of the Groups above, applicant is required to also elect a single sequence from the group of SEQ ID Nos. 5-14 if Group II is elected and one sequence each from the nucleic acid aptamer groups, SEQ ID Nos. 31-33 and 34-36, if Group III or Group IV is elected. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David C. Thomas
Patent Examiner
Art Unit 1637

David C. Thomas
3/14/06

[Signature]
JEFFREY FREDMAN
PRIMARY EXAMINER

3/14/06